TK 9/12/13

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF POLLUTION PREVENTION AND TOXICS

REGULATION OF NEW CHEMICAL SUBSTANCE

PENDING DEVELOPMENT OF INFORMATION

In the matter of:	)	Premanufacture Notice Number
	)	
	)	
	)	
	)	
	)	
[ ]	)	P-11-526
	)	
	)	
	)	
	)	
	)	

Consent Order and Determinations Supporting Consent Order

EPA SANITIZED

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I. INTRODUCTION

Under the authority of § 5(e) of the Toxic Substances Control Act ("TSCA") (15 U.S.C. 2604(e)), the Environmental Protection Agency ("EPA" or "the Agency") issues the attached Order, regarding premanufacture notice ("PMN") P-11-526 for the chemical substance [

CAS Registry Number [ ]

(the "PMN substance") submitted by [ ] ("the Company"), to take effect upon expiration of the PMN review period. The Company submitted the PMNs to EPA pursuant to § 5(a)(1) of TSCA and 40 CFR Part 720.

Under § 15 of TSCA, it is unlawful for any person to fail or refuse to comply with any provision of § 5 or any order issued under § 5. Violators may be subject to various penalties and to both criminal and civil liability pursuant to § 16, and to specific enforcement and seizure pursuant to § 17. In addition, chemical substances subject to an Order issued under § 5 of TSCA, such as this one, are subject to the § 12(b) export notice requirement.

II. SUMMARY OF TERMS OF THE ORDER

The Consent Order for the PMN substance requires the Company to:

(a) submit to EPA certain environmental fate and physical/chemical testing on the PMN substance, P-11-526, before [ ] after this Consent Order is signed and effective and certain toxicity and fate testing on the PMN substance and a degradant [

] of the PMN substance at least 14 weeks before manufacturing a total of [ ] kilograms (kgs) and [ ] kgs of the PMN substance;

(b) analyze and report to EPA [ ][1]* impurities;

(c) not exceed the maximum established levels of [ ] impurities; and

(d) maintain certain records.

Although a Consent Order for Contract Manufacturer is not attached to extend the requirements in this Order to an identified Contract Manufacturer, the Company may use a Contract Manufacturer in the future, if a modification of this Order to add a Consent Order for a Contract Manufacturer is approved and signed by EPA and signed by the Contract Manufacturer. This Consent Order establishes the requirements for the Company if a Contract Manufacturer manufactures the PMN substance. Prior to using a Contract Manufacturer, the Company must submit to EPA the Contract Manufacturer identity and other manufacturing process, and exposure, and release information concerning the Contract Manufacturer. The Contract Manufacturer would be required to keep records of quantities manufactured, but the Company must submit to EPA the required testing.

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[1] *As used in both the Preamble and Consent Order of this document, the terms [ ] mean [ ]

III. CONTENTS OF PMN

By signing this Order, the Company represents that it has carefully reviewed this document and agrees that all information herein that is claimed as confidential by the Company is correctly identified within brackets and that any information that is not bracketed is not claimed as confidential. To make this document available for public viewing, EPA will remove only information contained within the brackets.

Confidential Business Information Claims (Bracketed in the Preamble and Order): company identity, specific chemical identity, production volumes, manufacturing process, processing, and use information, and other information.

Chemical Identity:

Specific: [

CAS Registry Number [ ]

Generic: Amphoteric fluorinated surfactant

Use: Specific: [

:]

Generic use: Surface active agent

Maximum 12-Month Production Volume: [ ] kgs

Test Data Submitted with PMN and During the Review Period by this Company (many acronyms are subsequently explained more fully in section IV below where the results of the studies are discussed): Fish, daphnia, and algae screen, Formulation [ ]; Oral LD50, Skin and Eye Irritation, Local Lymph Node Assay, Bacterial Reverse Mutation, Acute Inhalation Toxicity, Chromosome Aberration mammalian cells, Forward Mutation in mammalian cells, Dermal LD50, 7-day Oral Toxicity range-finder and toxicokinetic behavior, 28-day oral toxicity study with a reproduction component, 48-hour Daphnia, 21-day Daphnia, 96-hour Trout, Fish Early Life Stage, trout (FELS) and includes a bioconcentration calculation submitted as Revision 1 of the FELS, 96-hour Zebrafish, 96-hour algae, Acute Toxicity Earthworm, Activated sludge respiration inhibition (screen), Ready biodegradability, Abiotic-Hydrolysis as a function of pH, Adsorption/desorption, self-ignition, Flashpoint of liquid suspension, all using Formulation [ ]; Physical-chemical properties using Formulation [ ]–melting point, decomposition temperature, water solubility, vapor pressure, octanol/water partition co-efficient, flammability, self-ignition, surface tension, relative density and dissociation constant.

Toxicity Studies on [ ] previously conducted, some submitted to EPA by this Company:

[ ] (1968) Acute Oral test [ ];
[ ] (2006) Bacterial reverse mutation test [ ] 20947;
[ ] (2006) In Vitro mammalian chromosome aberration test in human peripheral blood lymphocytes [ ]-20880;
[ ] (2006) Pilot developmental toxicity study in rats. Data are found in [ ]-22731;

[ ](2007) [ ] pilot in vitro rat hepatocyte screen [ ]-22731;
[ ] (2007) Developmental toxicity study in rats;]-11560 [ ]-24748: [ ] Screening 10-Dose Oral Gavage Study in Rats;
[ ]-18510 [ ]: Repeated Dose Oral Toxicity Two-Week Gavage Study 3 volumes;
[ ]-19715 [: Repeated dose, 90-day Study with Reproductive Screen;
Gannon, et al., (2011) Adsorption, distribution, metabolism, and excretion of [ ]-) in rats and mice. Toxicology 283, 55-6-2; and
Loveless, et al., (2009) Toxicological evaluation of sodium perfluorohexanoate Toxicology 264, 32-44.

IV. EPA'S ASSESSMENT OF EXPOSURE AND RISK

The following are EPA's predictions regarding the probable toxicity, human exposure and environmental release of the PMN substance, based on the information currently available to the Agency.

Human Health Effects and Fate Summary: EPA has concerns for potential incineration or other decomposition products or degradants of the PMN substance. EPA also has concerns for the PMN substance that under some conditions of use-- particularly non-industrial, commercial, or consumer use-- could cause lung effects, based on limited data on some perfluorinated compounds.

The Company has tested the PMN substance in animals. Data was submitted that addressed inhalation toxicity, systemic toxicity, sensitization, and irritation. An acute inhalation study was submitted and reviewed. The study test substance was on a formulation [

EPA reviewed the study and determined the LC50 of the PMN substance to be >1.568 mg/L (based on the [ ] PMN substance in the test substance).

The PMN substance was tested in a Local Lymph Node Assay (LLNA) with the test material [ ] at 5%, 25%, 50%, and 100%. The substance is not a skin sensitizer. In the skin and eye irritation studies, the PMN substance was not classified as a skin or eye irritant.

The Systemic Toxicity with a one-Generation Reproduction Study in Rats was reviewed by EPA. The test substance also contains [ ] PMN substance. The study methodology and results are acceptable. For systemic toxicity, the Lowest observed adverse effect level (LOAEL) is 50 mg/kg/day and the No observed adverse effect (NOAEL) is 10 mg/kg/day. The systemic toxicity findings are based on degeneration/atrophy of the olfactory lining of the nose and kidney effects. Further review by EPA did not find the effects on the nose to be significant. For Reproduction and Developmental Toxicity, no LOAEL was established. The NOAEL is 200 mg/kg/day which is the highest dose tested. The doses tested were 0, 10, 50, and 200 mg/kg/day which were selected from the 7-day study in rats. EPA finds that these effects are not similar to other [ ].

EPA expects that the PMN substance will degrade based on [ ]. The PMN substance may degrade to [ ], and other [ ] substances. Based on information submitted to EPA during the PMN review period, the PMN substance could have [

]. EPA has agreed that for routine analysis, the Company will analyze the starting material, the [ ] for the following analytes: the [ ]. The Company will also quarterly analyze the starting material,] for [ )], including establishing calibration curves. Also, at initial manufacture and at least annually thereafter, the Company has agreed to analyze representative samples of the "Initially Isolated Formulations"of the final formulation of the PMN substance. "Initially Isolated Formulations" is defined in the Definitions section of this Consent Order (Attachment A). The Company will analyze the Formulations for the [ ] and [ ]. For the Initially Isolated Formulations, [ ] should be [ ].

The Company will continue to work towards reducing the maximum amount of impurities [ ]. During commercial production, these impurities are produced partly by [ ] The Company has agreed to seek ways to minimize these impurities. The Company, in consultation with EPA, has agreed to [ ]. The Company is also evaluating other chemical management steps, which include [ ].

To further document and control the actual contamination and efforts to reduce the impurity

levels, the Company will limit the maximum impurity levels in the starting material, [ ] not to exceed the currently attainable levels (see Tables 1 and 2 in the Chemical Synthesis and Composition section of the attached Consent Order), and will analyze for and keep records of the various impurities [ ] quarterly (four times per year). The required quarterly sampling and analysis will be prospective from the date of analysis from a compliance perspective. The Company will report these levels annually to EPA. The Company will also monitor these impurities in the Initially Isolated Formulation.

EPA is concerned that perfluorinated degradation products may be released to the environment from use and degradation of the PMN substance. EPA has preliminary evidence, including data on other [ ], that suggests that, under some conditions, the PMN substance could degrade in the environment. In addition, the perfluorinated degradants are found near the sites of use for training and efficacy of the primary use for the PMN substance. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic (PBT) to people, wild mammals, and birds based on data on analogs including PFOA,] and potential degradants, [ ]. The presumed perfluorinated degradants for the PMN substance include [ ]. There is limited toxicological data in animals on [ ] and limited toxicological data in animals on [ ] or precursors, which is summarized below.

PFOA is expected to persist for years in the environment. Biodegradation and photolysis tests of analogous substances indicate little or no biodegradation or photolysis of perfluoroalkyl compounds. Bioaccumulation concerns are based on the measured presence of certain perfluoroalkyl compounds, including PFOA, in wildlife and in human blood samples. Toxicity studies on PFOA indicate developmental, reproductive and systemic toxicity in various species. Cancer may also be of concern. These factors, taken together, raise concerns for potential adverse chronic effects in humans and wildlife. For additional information about PFOA, consult the EPA regulatory docket at OPPT-2003-0012. Additional information about PFOA, [ ], and other perfluorinated substances may also be found in the *Administrative Record for PFOS, PFOA, and Telomers and Related Chemicals (AR-226).* *Administrative Record (AR-226)* is not currently available online, but copies can be requested on CD-ROM from the EPA Docket office by calling 202/566-0280 or sending an email request to oppt.ncic@epa.gov.

Limited toxicological, ecological, and fate data now exist on [ ] and some of the [ ]-derived polymers and other substances; see the PMN docket for data for these specific PMNs. A pharmacokinetics study on [ ] and for comparison perfluorobutane sulfonate (PFBS) in the cynomolgus monkey was submitted previously. This study indicates that the serum half-life of [ ] in these monkeys is less than 24 hours, whereas the half-life of PFOA in monkeys is 20.9 days in female monkeys, 32.6 days in male monkeys, and 3.8 years in humans. Another company also conducted a pharmacokinetics study on [ ] in rats that showed a serum half-life of one hour or less. These data and assessments support the assessment of reduced bioaccumulation of [ ] relative to PFOA.

The Company subject to this Consent Order has conducted a 90-day study with a reproductive screen on]. Dose levels for this study were 0, 20, 100, and 500 mg/kg/day. EPA received this study at the end of July 2007. EPA review of this study concluded that a no-observed adverse effect level (NOAEL) was not established in this study for systemic effects. There were numerous effects at 100 and 500 mg/kg/day on nasal tissue, liver, and thyroid, and at 500 mg/kg/day on body weight, the red blood cell system, clotting, and the kidney. The EPA reviewer concluded that although not clearly dose related, the elevation of two markers for liver toxicity across all treated groups of males in clinical chemistry, and the finding of focal necrosis in the liver across all treated groups of males, as well as, in treated recovery males, and the absence of this result in the controls, leads to the conclusion that no NOAEL was achieved.

For the one-generation reproductive toxicity study component of this study, the reproductive toxicity NOAEL is 500 mg/kg/day (the highest dose tested). The systemic toxicity NOAEL for P1 rats was 20 mg/kg/day based on decreased body weights/body weight gains at 100 and 500 mg/kg/day. The systemic toxicity NOAEL for F1 adults is 100 mg/kg/day based on reduced body weights/body weight gains and reduced food consumption at 500 mg/kg/day. The developmental toxicity NOAEL for F1 pups was 100 mg/kg/day based on decreased pup weights at 500 mg/kg/day. The rats (P1 generation; 20/sex/group) were administered gavage doses of 0, 20, 100 or 500 mg/kg/day for 70 days pre-mating, and then mated for a maximum of 2 weeks to produce 1 litter. Dosing was continued during mating, gestation, and lactation.

In addition, in 2005, another company conducted a Combined Repeated-Dose Toxicity Study with Reproduction/Developmental Screening Test, (OECD 422) in rats for] and the [ ]. The EPA review of these subchronic and reproductive data on] and the [ ] concluded that for [ ] no reproductive effects were seen at any dose. Dose levels were 50, 150, and 450/300 mg/kg/day (450 was reduced to 300 in the study on day 4 because of toxicity). However, systemic effects–primarily liver effects--were seen. EPA review places the NOAEL for [ ] at 50 mg/kg/day. For the [ ], the doses were 25, 75, and 225 mg/kg/day. For systemic effects, no NOAEL was achieved with the Lowest-Observed Adverse Effect Level (LOAEL) at 25 mg/kg/day. For reproductive or developmental effects, the NOAEL is 75 mg/kg/day and the LOAEL is 225 mg/kg/day.

In 2006, another company submitted a 90-day Oral Repeated Dose Toxicity Study (OECD 408) for [ ]. Dose levels for this study were 0 (vehicle control), 10, 50, or 200 mg/kg/day and were based on the previous Combined Study (OECD 422). EPA review set the Lowest- Effect Level (LOEL) or LOAEL at 10 mg/kg/day, based on the body weight gain being lower in all treated groups of males. There was treatment-related toxicity in the liver and the red blood cell system (anemia) in males at 200 mg/kg/day. There was also increased peroxisomal beta oxidation activity at this dose level. Hepatotoxicity and peroxisomal beta oxidation activity have also been seen in studies on PFOA.

The significance of the finding of a benign brain tumor (astrocytoma) in one male rat in the high dose group is not clear. It is not the type of tumor normally associated with PFOA-type compounds, is not a rare tumor, and may be incidental. Abnormal histopathology was observed

in the testes (2 males) and epididymides (1 male) at 200 mg/kg/day and is a sign of concern for male reproductive toxicity. Further testing should investigate male reproductive effects. From this study, the potential for immunotoxic effects is low. There have been some studies showing immunotoxic effects from PFOA. Any investigation of immunotoxic effects should await the corroborative testing now being conducted by EPA, Office of Research and Development. There were no clinical signs of neurotoxicity and there were no treatment-related effects in the functional observation battery or motor behavior.

Another 90-day study has been submitted to EPA on [ ]. EPA review of that study concluded that blood and liver effects were seen at the highest dose. This study had comparable doses with the other studies.

EPA received a Chronic Toxicity/Carcinogenicity study on [ ] in 2011. Doses were 2.5, 15, and 100 mg/kg/day for males and 5, 30, and 200 mg/kg/day for females. EPA review determined that no chronic toxicity or carcinogenicity effects were seen in the two lower doses. Due to limitations in the study no determination could be made for the highest doses.

EPA has also received a modified reproductive study (OECD 421,modified). The modifications for the reproductive test include: (1) increase the parental sample size to 20; (2) the duration of the study should be extended to until the pups have reached sexual maturation; (3) parental males should be dosed for 10 weeks prior to mating; (4) dosing of the parental animals should be continued through lactation and then the pups should be directly dosed until they reach sexual maturation; (5) pup body weight should be recorded on lactation days 0, 4, 7, 14, and 21, and then at weekly intervals, (6) litter size can be standardized to 4 pups/litter on lactation day 4

(optional); (7) at weaning one pup/sex/litter can be randomly selected to follow until sexual maturation; and (8) the time of sexual matuation should be recorded (i.e. vaginal opening and preputial separation).

A one-generation reproduction/developmental toxicity study in mice on the ammonium salt of] (OECD 421, modified) as described above was submitted to the Agency. In this study, pregnant mice were administered the test substance via gavage during gestation days 6-18. The NOAEL for maternal toxicity was 175 mg/kg/day (the highest dose tested). Signs of developmental toxicity were observed at 175 mg/kg/day on the postnatal day 1 and consisted of increases in the number of stillborn pups and pup deaths, reductions in the average pup body weight per litter, and a pup with lenticular opacity. The NOAEL for developmental toxicity is 35 mg/kg/day.

Limited toxicological data exist on what may be a persistent degradant of the PMN substance,]. A 14-day oral toxicity study on male mice with the [ ] was conducted. The study established a LOAEL of 45 mg/kg/day (300 ppm) based on observations of liver discolorations and increased mean absolute and relative liver weights and a NOAEL of 4.5 mg/kg/day (30 ppm). In addition, a 14-day oral toxicity study on male rats with the same test substance and doses was conducted. EPA concluded that the LOAEL is 30 ppm, the lowest dose tested based on significant increases in the mean relative liver weights and the lack of experimental observations (hematology, gross patholgy, etc) allowing determination of whether

the elevation in relative liver weights is an adaptive or adverse change and making inferences on the significance of the reversibility of the change.

These and other data indicate a different and less toxic profile for] (a possible environmental degradant of the PMN substance) than for PFOA. In addition, [ ] has not been tested in a 28-day or a 90-day systemic toxicity test or a reproduction study. Therefore, based on: (1) the environmental persistence of [ ]; (2) potential intermediate fate products; and, (3) the possibility or likelihood that this substance may be used as a major substitute for some uses of PFOA, EPA believes that more information is needed on the toxicity of the PMN substance and] and possibly other environmental degradants, and the fate and physical/chemical properties of [ ]-derived or related chemical substances in the environment. More data on the PMN substance could be necessary if new information comes to light on the PMN substance or its potential degradants.

EPA also believed that additional reproductive and long-term toxicological testing on [ ] and the PMN substance in animals was warranted. To this end, the Company has conducted a 90-day Repeated Dose Study With Reproductive Screen on [ ]. An avian reproduction test (bobwhite quail) (OECD 206) was also be conducted by another company on [ ]. EPA may still seek additional avian reproduction testing (OECD 206) in mallard ducks on [ ]. The Company is required to submit additional testing on the PMN substance and [ ]. In addition, comparative data, especially on the pharmacokinetics of [ ] and other perfluorinated substances will be developed by testing of the National Toxicology Program (NTP) in the so-called Perfluorinated Compounds Class Study.

Environmental Effects Summary: EPA expects the PMN substance or the degradants to be highly persistent. The Company performed and submitted fish (rainbow trout) and daphnia acute studies, the fish early life study (FELS) in rainbow trout, chronic daphnia, and algae tests. All five tests are acceptable per the EPA review.

For the Acute Fish test, there were no mortalities or sublethal effects at any dose and the 96-hour LC50 is >120 mg/L. In the Acute Daphnia test, the doses (adjusted for [ ] PMN substance with measured concentrations) were 0, control, 9.18, 16.7, 33.9, 67.3, and 122 mg/L. Daphnids were observed for mortality and visible abnormalities at 24 and 48 hours. Sub-lethal effects were seen at 33.9, 67.3 and 122 mg/L. The 48-hour EC50 is >122 mg/L with the NOEC at 16.7 mg/L and the LOEC at 33.9 mg/L. Two chronic tests were performed. In the Fish Early Life Stage test performed on rainbow trout, the endpoints assessed were hatching, growth, and survival of embryos. The test concentrations (adjusted for [ ] purity and measured concentrations) were 0.648,1.21, 2.69, 5.86, and 13.4 mg/L. The 90-day NOEC was 5.8 mg/L while the LOEC was 13.4 mg/L. In the 21-day Daphnid Test, daphnia were exposed for 21 days under static-renewal conditions. The test was conducted in accordance with the OECD 211 guideline. The test concentrations were 0 (control), 0.619, 1.50, 3.18, 6.42, and 13.5 mg/L (adjusted for % PMN substance and measured concentrations). Observations on immobilization, reproduction, and sub-lethal effects were taken daily. Length and dry weight of surviving adult daphnids were taken at the end of the test. Twenty percent adult mortality was observed in the highest test concentration at 21 days. The 21-day NOEC was 3.18 mg/L (survival of young),

while the LOEC was 6.42 mg/L (survival of young). The 21-day GMATC value was 4.52 mg/L. The 21-day EC50 is > 13.5 mg/L.

Based on these data, the chronic concentrations of concern (COC) is 452 ppb. This is derived by using the GMATC value for the survival of young in the 21-day daphnid test (4.52 mg/L) and then an assessment value of 10 is added which equals 452 ppb. The acute COC is 3,125 ppb. This is derived from the 96-hour algal value for a yield of 12.5 mg/L. This value is divided by an assessment factor of 4 for the species resulting in an acute COC of 3.125 mg/L or 3,125 ppb. EPA estimated releases to water do not exceed the COC.

In the Algae Test, green algae were exposed to the PMN test material [ ] PMN substance for 96 hours. The nominal concentrations (adjusted for [ ] PMN substance mean measured concentrations were 1.8, 3.43, 7.19, 15.8, and 31.6 mg/L. At 96 hours, the EC 50 was >31.6 mg/L. The most sensitive species was daphnia.

EPA received the Avian Reproduction Test on [ ] in late 2011. The test was conducted according to OPPTS 850.2300, OECD 206 and FIFRA Subdivision E Section 71-4 guidelines and under GLP conditions. Results showed no adverse effects in adult northern bobwhite quail exposed to 1,000 ppm, 5,000 ppm or 10,000 ppm for body weight, feed consumption, or reproductive parameters. In addition, no effects were observed in the offspring of the exposed adults. The NOEC is 10,000 ppm or 964 mg/kg/day. Although the original test recommendations included analysis for [ ] of the livers of the adult birds as well as the blood and livers of the offspring for the presence of [ ], the fact that the analysis was not performed will not alter the validation of the study considering the lack of effects seen in adult

tissue at necropsy and the lack of signs of toxicity in both the adult and offspring as a whole. In summary, the NOEC remains 10,000 ppm or 964 mg/kg/day.

In addition, there is high concern for possible environmental effects from the potential persistent degradation product [ ] and [ ]. Some acute ecotoxicity (fish, daphnia, and algae) and a chronic fish test exists on [ ] which were conducted in 2007. The fish 96-hour LC50 is greater than 107 mg/L, the daphnia 48-hour EC50 is 109 mg/L, and the algal EC50 is greater than 95.6 mg/L with an Algal chronic value of 67.6 mg/L. In addition, an early life stage fish test was conducted on the [ ]. The NOEC was 2.62 mg/L with a LOEC of 4.85 mg/L and a chronic value or a GMATC of 3.36 mg/L.

As stated previously, the analog PFOA is persistent in the environment and has a long bioretention time in various species. It has been detected in a number of species of wildlife, including marine mammals. It is toxic to mammalian and other species. The presence in the environment and toxicological properties of PFOA continue to be investigated. Some acute ecotoxicological effects data also exist on [ ] in fish, daphnia, and algae. EPA believed development of additional chronic data on [ ] was warranted. These studies were conducted by other companies and the Avian Reproduction study as described above.

Fate in the Environment and Fate Testing: A Ready biodegradation study, Adsorption desorption study, Activated Sludge respiration test, and a hydrolysis test were conducted on the PMN substance. The Ready biodegradation and hydrolysis tests indicated that the PMN substance

may not biodegrade. However, there were issues concerning recovery of the test material in the hydrolysis test and it has been determined that the Ready biodegradation study is not an appropriate test to evaluate slower degradation over time. EPA is requiring fate and physical/ chemical testing on the PMN substance.

Exposure and Environmental Release Summary: Thermal and simulated incineration testing exists on some related substances. This testing indicates that incomplete incineration products are formed at lower incineration temperatures. EPA has determined that the PMN substance may degrade. This conclusion is based on monitoring data at sites of use with substances similar in use and structure of the PMN substance.

The PMN substance is expected to be manufactured and processed in the United States. The PMN substance is manufactured at a [ ] where the PMN substance will primarily be disposed of by incineration. The PMN substance has a total of [ ] end-uses with one primary use, [ ]. The PMN substance will be used as [ ] For the primary use, it is sold by [ ] to processors that will process the PMN substance presently at [ ] sites. For the primary use, the PMN substance will be further diluted in the [ ] formulations that are formulated by customers of [ ] to a percentage of approximately [ ] which is further diluted resulting in a final end-user concentration of [As an [ ], the PMN

substance is in formulations of [ ]. As a [ ] the PMN substance is a [ ] and used at less than [ ]

Use as a [ ] could be considered a dispersive use and if used could potentially all go to the environment. It is used at [ ] and other entities. It is used at training sites and for [.] Human occupational exposure could be dermal exposure to liquids or [ ]. Releases to the environment were estimated for manufacturing, processing, use. Over [ ] is ultimately disposed by incineration and/or landfill when the [ ] expires. The remaining amount of the production volume may be released to water. A predominance] of the PMN substance is processed into [ ] [ ] processing sites were assessed. All of the PMN substance could be released into the environment, if used. Several scenarios of use and potential release were assessed including use at training sites. There may be a periodic water release of [.] [ ] systems have to be periodically tested and some minimal releases to the environment may occur.

During use of the PMN substance in [ ], commercial users could be exposed via dermal and inhalation routes. In addition, there could be inhalation exposure to consumers during use in [ ]. EPA considers this exposure to be episodic exposure. The EPA exposure estimate to consumers for use as an [ ] for the PMN substance gives a peak concentration of 0.035 mg/m3.

Based on the acute inhalation study of a formulation containing [ ] PMN substance, the LC50

for P-11-526 from a 4-hour inhalation study in rats is greater than 1.568 mg/L. This value can be used to assess the risk of exposure to consumers from spray applications of products that contain the PMN substance. For all uses that are episodic in nature and would occur only a limited number of times per year, a New Chemical Exposure Limit (NCEL) for acute exposures is set a 15 mg/m3. Since the peak concentration of 0.035 mg/m3 is significantly less than 15 mg/m3, there is a low potential for risk from acute, episodic exposures.

During use as a [ ], the PMN substance] is metered from totes to a mixing truck and mixed into a fluid]. The exposure is via the dermal route and releases may go to water or be incinerated or landfilled for 1 day per year.

V. EPA'S CONCLUSIONS OF LAW

The following findings constitute the basis of the Consent Order:

(a) EPA is unable to determine the potential for human health and environmental effects from exposure to the PMN substance and potential degradation products. EPA therefore concludes, pursuant to § 5(e)(1)(A)(i) of TSCA, that the information available to the Agency is insufficient to permit a reasoned evaluation of the human health and environmental effects of the PMN substance and potential degradation products.

(b) In light of the potential risk of human health and environmental effects posed by the uncontrolled manufacture, processing, distribution in commerce, use, and disposal of the PMN substance, EPA has concluded, pursuant to § 5(e)(1)(A)(ii)(I) of TSCA, that uncontrolled

manufacture, processing, distribution in commerce, use, and disposal of the PMN substance may present an unreasonable risk of injury to human health and the environment

c) In light of the estimated production volume of, and human exposure to, the PMN substance, P-11-526 and potential degradation products, EPA has further concluded, pursuant to § 5(e)(1)(A)(ii)(II) of TSCA, that the PMN substance will be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substance and potential degradation products.

VI. INFORMATION REQUIRED TO EVALUATE HUMAN HEALTH AND ENVIRONMENTAL EFFECTS

Triggered Testing. The Order requires certain fate testing within 1 year of when this Order is executed and prohibits the Company from exceeding specified production volumes unless the Company submits the information described in the Testing section of this Order in accordance with the conditions and test substance specified in the Testing section. The physical properties of the PMN substance and target analytes present technical challenges in conducting the required testing. EPA will review submitted protocols in a timely fashion as stated in the Consent Order and provide additional relevant information and input to the extent that it is known and not claimed confidential by other companies.

Pending Testing. The Order does not require submission of the following information at any specified time or production volume. However, the Order's restrictions on manufacture, processing, distribution in commerce, use, and disposal of the PMN substance will remain in

effect until the Order is modified or revoked by EPA based on submission of the following or other relevant information.

EPA expects that protocols would be submitted prior to any additional toxicological testing required under this Consent Order. Due to the limited water solubility of some of these substances and consequent analytical difficulties, some modification of the protocols may be necessary. These and other modifications will be agreed upon between EPA and the Company.

Information on inhalation toxicology if the substance had additional uses and was to be sprayed by [

]. This could include a repeated dose inhalation study with a bronchoalveolar lavage component and special attention to histopathology (inflammation and cell proliferation) or other relevant information.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

CONSENT ORDER

I. SCOPE OF APPLICABILITY AND EXEMPTIONS

(a) Scope. The requirements of this Order apply to all commercial manufacturing (which includes importation), processing, distribution in commerce, use and disposal of the following chemical substance: [ ], CAS Registry Number [ ] P-11-526, (the "PMN substance") in the United States by [ ] ("the Company"), except to the extent that those activities are exempted by paragraph (b).

(b) Exemptions. Manufacturing of the PMN substance is exempt from the requirements of this Order (except the requirements in the Recordkeeping and Successor Liability Upon Transfer Of Consent Order sections) only to the extent that (1) these activities are conducted in full compliance with all applicable requirements of the following exemptions, and (2) such compliance is documented by appropriate record keeping as required in the Recordkeeping section of this Order.

(1) Export. Until the Company begins commercial manufacture of the PMN substance for

use in the United States, the requirements of this Order do not apply to manufacture, processing or distribution in commerce of the PMN substance solely for export in accordance with TSCA §12(a) and (b), 40 CFR 720.3(s) and 40 CFR Part 707. However, once the Company begins to manufacture the PMN substance for use in the United States, no further activity by the Company involving the PMN substance is exempt as "solely for export" even if some amount of the PMN substance is later exported. At that point, the requirements of this Order apply to all activities associated with the PMN substance while in the territory of the United States. Prior to leaving U.S. territory, even those quantities or batches of the PMN substance that are destined for export are subject to terms of the Order, and count towards any production volume test triggers in the Testing section of this Order.

(2) Research & Development ("R&D"). The requirements of this Order do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substance in small quantities solely for research and development in accordance with TSCA §5(h)(3), 40 CFR 720.3(cc), and 40 CFR 720.36. The requirements of this Order also do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substance when they are manufactured solely for non-commercial research and development per 40 CFR 720.30(i) and TSCA §5(i).

(3) Byproducts. The requirements of this Order do not apply to the PMN substance when they are produced, without separate commercial intent, only as a "byproduct" as defined at 40 CFR 720.3(d) and in compliance with 40 CFR 720.30(g).

(4) No Separate Commercial Purpose. The requirements of this Order do not apply to the PMN substance when they are manufactured, pursuant to any of the exemptions in 40 CFR 720.30(h), with no commercial purpose separate from the substance, mixture, or article of which

they are a part.

(5) Imported Articles. The requirements of this Order do not apply to the PMN substance when they are imported as part of an "article" as defined at 40 CFR 720.3(c) and in compliance with 40 CFR 720.22(b)(1).

(c) Automatic Sunset. If the Company has obtained for the PMN substance a Test Market Exemption ("TME") under TSCA §5(h)(1) and 40 CFR 720.38 or a Low Volume Exemption ("LVE") or Low Release and Exposure Exemption ("LoREX") under TSCA §5(h)(4) and 40 CFR 723.50(c)(1) and (2) respectively, any such exemption is automatically rendered null and void as of the effective date of this Consent Order.

II. TERMS OF MANUFACTURE, IMPORT, PROCESSING, DISTRIBUTION IN COMMERCE, USE, AND DISPOSAL PENDING SUBMISSION AND EVALUATION OF INFORMATION

PROHIBITION

The Company is prohibited from manufacturing the PMN substance in the United States, for any nonexempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the human health and environmental effects of the substances, and the completion of EPA's review of, and regulatory action based on, that information, in accordance with the conditions described in this Order.

CHEMICAL SYNTHESIS AND COMPOSITION

(a) Restriction. The Company shall not manufacture the PMN substance, P-11-526 unless the [ ] starting material is in compliance with the limits specified in Table 1 and Table 2.

The Company shall analyze the Initially Isolated Formulations of the PMN substance for the analytes specified in Table 3 upon initial commencement of manufacture, and at least annually analyze and report thereafter, until one year after the date of the last joint manufacture or processing of a product that contains] products at the facility. The Company shall report annually to the Agency the levels of impurities [ ] associated with the PMN substance, P-11-526 manufactured by the Company, as specified below. For routine analysis, the Company shall analyze the starting material, [ ] for the following analytes shown in Table 1 below: [ )]. The Company will also quarterly analyze the starting material, [ ], for the analyte [ ] shown in Table 2, below. The Company shall make its best effort to minimize these impurities and to seek to eliminate them.

(b) Analysis and Reporting. The Company shall analyze representative samples of the Initially Isolated Formulations of the PMN substance, P-11-526 manufactured by the Company to determine compliance with the requirements in paragraph (a). The Company shall also analyze the Initially Isolated Formulations of the PMN substance at each manufacturing facility both (1) at the initial commencement of non-exempt manufacture of the PMN substance at that facility, and (2) at least annually thereafter during every year in which the PMN substance is manufactured at that facility or imported. If any new facility of manufacture is added or if the process of manufacture of the PMN substance is significantly altered, then the Initially Isolated Formulation of the PMN substance must be analyzed at commencement, and annually thereafter as set forth above. If the PMN substance is imported, the Company shall obtain from the foreign manufacturer written documentation to certify that representative samples of the imported form of

the PMN substance have been analyzed, consistent with the requirements of this paragraph (b), and determined to comply with the requirements of paragraph (a). The Company shall report the above analysis to EPA at initial commencement of manufacture and again if any new manufacturing facility is added or if the process of manufacture of the PMN substance or any intermediate thereof is significantly altered. The Company shall continue to report these impurity levels to EPA annually, in a cycle complementary to the [

]. In addition to the reporting for the Initially Isolated Formulations of the PMN substance themselves, the Company shall, for the [ ] starting material, annually report (1) the average values and the range of values, including outlying data, for the routine analysis for the analytes specified in Table 1 and (2) the results of the quarterly analyses for the analyte specified in Table 2.

TABLE 1:

TO BE ROUTINELY ANALYZED IN [ ] STARTING MATERIAL

Analyte	CAS Number	Limit in [ ]
[ ] (intended	[ ]	[ ] minimum
[ ] [ ]	[ ]]	] (combined)

TABLE 2:

TO BE ANALYZED AT LEAST QUARTERLY IN [ ] STARTING MATERIAL

Analyte	CAS Number	Limit in [

TABLE 3:
TO BE ANALYZED AT START-UP AND AT LEAST ANNUALLY THEREAFTER IN THE INITIALLY ISOLATED FORMULATIONS OF THE PMN SUBSTANCE

Analyte	CAS Number	Estimated Maximum in Initially Isolated Formulations of the PMN substance
[ ] [ ]	[ ] [ ]	[ ] (combined)
[ ]	[ ]	[ ]

MANUFACTURING

(a)(1) Prohibition. The Company shall not cause, encourage, or suggest the manufacture of the PMN substance by any other person. However, the Company may communicate to any other person the existence of the 5(e) Consent Order and TSCA Inventory status for the PMN substance.

(2) Sunset Following SNUR. Subparagraph (a)(1) shall expire 75 days after promulgation of a final significant new use rule ("SNUR") governing the PMN substance under section 5(a)(2) of TSCA unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, subparagraph (a)(1) shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(3) Notice of SNUR. When EPA promulgates a final SNUR for the PMN substance and subparagraph (a)(1) expires in accordance with subparagraph (a)(2), the Company shall notify each person whom it causes, encourages or suggests to manufacture or import the PMN

substance of the existence of the SNUR.

(b) Contract Manufacturer. Notwithstanding paragraph (a), the Company may cause a "Contract Manufacturer" outside the Company to manufacture the PMN substance according to the following conditions:

(1) The Contract Manufacturer must be under contract to the Company to manufacture or import the PMN substance solely for the Company. The contract must specify the identity of the PMN substance, the total quantities to be manufactured, and the basic technology to be used for manufacturing.

(2) The Company shall obtain from each Contract Manufacturer a signed copy of the Consent Order for Contract Manufacturer (to be attached to this Order as Attachment C) and submit the copy to EPA along with the name, address, and telephone number of a responsible official of the Contract Manufacturer. The Contract Manufacturer or Company must receive a fully executed copy of the Consent Order for Contract Manufacturer from EPA before the Contract Manufacturer may begin manufacture or import.

(3) If at any time, the Company learns that the Contract Manufacturer has failed to comply with any of the conditions specified in the Consent Order for Contract Manufacturer, the Company shall immediately cease to cause the Contract Manufacturer to manufacture the PMN substance, unless the Contract Manufacturer is in compliance with a SNUR for the PMN substance, or unless the Company is able to document each of the following:

(i) That the Company has, within 5 working days, notified the Contract Manufacturer in writing that the Contract Manufacturer has failed to comply with any of the conditions specified in the Consent Order for Contract manufacturer.

(ii) That, within 15 working days of notifying the Contract Manufacturer of the

noncompliance, the Company received from the Contract Manufacturer, in writing, a statement of assurance that the Contract Manufacturer is aware of the terms of the Consent Order for Contract Manufacturer and will comply with those terms.

(iii) If, after receiving a statement of assurance from the Contract Manufacturer under subparagraph (b)(ii) of this Section, the Company has notice or knowledge that the Contract Manufacturer has failed to comply with any of the conditions specified in the Consent Order for Contract Manufacturer, the Company shall immediately cease to cause the Contract Manufacturer to manufacture or import the PMN substance, shall notify EPA of the failure to comply, and shall resume causing the Contract Manufacturer to manufacture or import the PMN substance only upon written notification from the Agency.

DISTRIBUTION

(a) Export Notice Requirement. No later than the date of distribution, the Company shall notify in writing any person to whom it distributes the PMN substance for "commercial use" or "industrial use" that, due to the issuance of this Consent Order under section 5(e) of TSCA, the PMN substance are subject to the export notification requirements of TSCA section 12(b) and 40 CFR Part 707 Subpart D. Such notice shall contain, in the form in which it appears in this Consent Order, the following information: (1) the PMN number, and (2) either (A) the specific chemical identity of the PMN substance, or (B) if the specific chemical identity is confidential, the generic chemical identity.

TESTING

(a). Section 8(e) Reporting. Reports of information on the PMN substance which reasonably supports the conclusion that the PMN substance present a substantial risk of injury to health or

the environment, which is required to be reported under TSCA section 8(e) shall reference the appropriate PMN identification number for these substances and contain a statement that the substances are subject to this Consent Order. Additional information regarding section 8(e) reporting requirements can be found at www.epa.gov/oppt/tsca8e.

(b) Notice of Study Scheduling. The Company shall notify, in writing, the EPA Laboratory Data Integrity Branch (2225A), Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460, of the following information within 10 days of scheduling any study required to be performed pursuant to this

Order, or within 15 days after the effective date of this Order, whichever is later:

(1) The date when the study is scheduled to commence;

(2) The name and address of the laboratory which will conduct the study; and

(3) The name and telephone number of a person at the Company or the laboratory whom EPA may contact regarding the study.

(4) The appropriate PMN identification number for each substance and a statement that the substance is subject to this Consent Order.

(c) Good Laboratory Practice Standards and Test Protocols. Each study required to be performed pursuant to this Order must be conducted according to TSCA Good Laboratory Practice Standards at 40 CFR Part 792 and using methodologies generally accepted in the relevant scientific community at the time the study is initiated. Before starting to conduct any study, the Company must obtain approval of test protocols from EPA by submitting written

protocols. EPA will respond to the Company within 4 weeks of receiving the written protocols. Published test guidelines specified in paragraph (d) provide general guidance for development of test protocols, but are not themselves acceptable protocols. Approval of the test protocol does not mean pre-acceptance of test results.

(d) Triggered Testing Requirements. (i) The Company is prohibited from manufacturing the PMN substance, unless the Company conducts the following studies and submits final reports and underlying data in accordance with the production limits specified in this testing section (i.e.) beyond [ ] after the signature by both parties of this Order for certain studies and beyond the aggregate manufacture and import volumes of [ ] kilograms, and [ ] kilograms for other studies.

Production Limit	Study	Guideline
[(after signature of Order)	Zahn-Wellens Biodegradation Study with Analysis for Degradation Products as specified	OPPTS 835.3200 OECD 302B
	Hydrolysis as a function of pH and temperature	OPPTS 835.2130, OECD 111
[kgs	90-day repeated dose oral toxicity study in rats with 1-generation reproduction parallel (Must include modifications) [ ]	OPPTS 870.3100 and OECD 421, Modified
	Soil Biodegradation Study	OECD 307
] kgs	UV visible light absorption	OPPTS 830.7050, OECD 101
	Direct Photolysis, if wavelengths greater than 290 nm are absorbed in the previous test (OPPTS 830.7050)	OPPTS 835.2210

Indirect Photolysis Screening Test	OPPTS 835.5270
Anaerobic Biodegradability of Organic Compounds in Digested Sludge	OECD 311
Avian Reproduction in bobwhite quail	OPPTS 850.2300

(ii) The test substance shall be the PMN substance described in P-11-526 and [

for the 90-day toxicity study as specified. Chemical composition of the test substance shall be verified and a certificate of analysis submitted to EPA.

(iii) Chemical composition of the test substance must be fully characterized. For polymers, characterization includes all information required on pages 5 and 6 of the PMN form (i.e. EPA Form 7710-25), except that data on residuals are only required for fluorinated substances. Although EPA understands that complete mass balance may not be achievable for the specified analytes, the Company shall attempt mass balance to the greatest extent practicable. EPA prefers that the Company test the commercial substance.

(iv) The Company must test for the following analytes in the Zahn-Wellens Biodegradation test (OPPTS 835.3200, OECD 302B), the additional Biodegradation tests (OECD 307, and 311), and the Photolysis tests (OPPTS 835.2210 and 835.5270): [

), CAS Number

H), CAS Number , CAS Number ; CAS Number

, CAS Number ; , CAS Number

CAS Number), CAS

Number :

CAS Number

, known as .]

(v) Modifications for 90-day and OECD 421, modified: The modifications for the reproductive test include: (1) increase the parental sample size to 20; (2) the duration of the study should be extended to until the pups have reached sexual maturation; (3) parental males should be dosed for 10 weeks prior to mating; (4) dosing of the parental animals should be continued through lactation and then the pups should be directly dosed until they reach sexual maturation; (5) pup body weight should be recorded on lactation days 0, 4, 7, 14, and 21, and then at weekly intervals, (6) litter size can be standardized to 4 pups/litter on lactation day 4 (optional); (7) at weaning one pup/sex/litter can be randomly selected to follow until sexual maturation; and (8) the time of sexual maturation should be recorded (i.e. vaginal opening and preputial separation).

(e) Test Reports. The Company shall: (1) conduct each study in good faith, with due care, and in a scientifically valid manner; (2) promptly furnish to EPA the results of any interim phase of each study; and (3) submit, in triplicate (with an additional sanitized copy, if confidential business information is involved), the final report of each study and all underlying data ("the report and data") to EPA prior to exceeding the applicable production limit except for the first production limit which will be [ ] after signature of the Order. The final report shall contain the contents specified in 40 CFR 792.185. Underlying data shall be submitted to EPA in accordance with the applicable "Reporting," "Data and Reporting," and "Test Report" subparagraphs in the applicable test guidelines. However, for purposes of this Consent Order,

the word "should" in those subparagraphs shall be interpreted to mean "shall" to make clear that the submission of such information is mandatory. EPA will require the submission of raw data such as slides and laboratory notebooks only if EPA finds, on the basis of professional judgment, that an adequate evaluation of the study cannot take place in the absence of these items.

(f) Testing Waivers. The Company is not required to conduct a study specified in paragraph (d) of this Testing section if notified in writing by EPA that it is unnecessary to conduct that study.

(g) Equivocal Data. If EPA finds that the data generated by a study are scientifically equivocal, the Company may continue to manufacture and import the PMN substance beyond the applicable production limit. To seek relief from any other restrictions of this Order, the Company may make a second attempt to obtain unequivocal data by reconducting the study under the conditions specified in paragraphs (b), (c), and (e)(1) and (e)(2). The testing requirements may be modified, as necessary to permit a reasoned evaluation of the risks presented by the PMN substance, only by mutual consent of EPA and the Company.

(h) EPA Determination of Invalid Data.

(1) Except as described in subparagraph (h)(2), if, within 6 weeks of EPA's receipt of a test report and data, the Company receives written notice that EPA finds that the data generated by a study are scientifically invalid, the Company is prohibited from further manufacture and import of the PMN substance beyond the applicable production limit.

(2) The Company may continue to manufacture the PMN substance beyond the applicable production limit only if so notified, in writing, by EPA in response to the Company's

compliance with either of the following subparagraphs (h)(2)(i) or (h)(2)(ii).

(i) The Company may reconduct the study in compliance with paragraphs (b), (c), and (e)(1) and (e)(2). If there is sufficient time to reconduct the study and submit the report and data to EPA at least 14 weeks before exceeding the production limit as required by subparagraph (e)(3), the Company shall comply with subparagraph (e)(3). If there is insufficient time for the Company to comply with subparagraph (e)(3), the Company may exceed the production limit and shall submit the report and data in triplicate to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (h)(1). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data.

(ii) The Company may, within 4 weeks of receiving from EPA the notice described in subparagraph (h)(1), submit to EPA a written report refuting EPA's finding. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report.

(i) Company Determination of Invalid Data.

(1) Except as described in subparagraph (i)(2), if the Company becomes aware that circumstances clearly beyond the control of the Company or laboratory will prevent, or have prevented, development of scientifically valid data under the conditions specified in paragraphs (c) and (e), the Company remains prohibited from further manufacture and import of the PMN substance beyond the applicable production limit.

(2) The Company may submit to EPA, within 2 weeks of first becoming aware of such circumstances, a written statement explaining why circumstances clearly beyond the control of the Company or laboratory will cause or have caused development of scientifically invalid data. EPA will notify the Company of its response, in writing, within 4 weeks of receiving the

Company's report. EPA's written response may either:

(i) allow the Company to continue to manufacture the PMN substance beyond the applicable production limit, or

(ii) require the Company to continue to conduct, or to reconduct, the study in compliance with paragraphs (b), (c), and (e)(1) and (e)(2). If there is sufficient time to conduct or reconduct the study and submit the report and data to EPA at least 14 weeks before exceeding the production limit as required by subparagraph (e)(3), the Company shall comply with subparagraph (e)(3). If there is insufficient time for the Company to comply with subparagraph (e)(3), the Company may exceed the production limit and shall submit the report and data in triplicate to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (i)(2). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data, as to whether the Company may continue to manufacture and import beyond the applicable production limit.

(j) Unreasonable Risk.

(1) EPA may notify the Company in writing that EPA finds that the data generated by a study are scientifically valid and unequivocal and indicate that, despite the terms of this Order, the PMN substance will or may present an unreasonable risk of injury to human health or the environment. EPA's notice may specify that the Company undertake certain actions concerning further testing, manufacture, processing, distribution, use and/or disposal of the PMN substance to mitigate exposures to or to better characterize the risks presented by the PMN substance. Within 2 weeks from receipt of such a notice, the Company must cease all manufacture, processing, distribution, use and disposal of the PMN substance, unless either:

(2) within 2 weeks from receipt of the notice described in subparagraph (j)(1), the Company complies with such requirements as EPA's notice specifies; or

(3) within 4 weeks from receipt of the notice described in subparagraph (j)(1), the Company submits to EPA a written report refuting EPA's finding and/or the appropriateness of any additional requirements imposed by EPA. The Company may continue to manufacture, process, distribute, use and dispose of the PMN substance in accordance with the terms of this Order pending EPA's response to the Company's written report. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report. Within 2 weeks of receipt of EPA's written response, the Company shall comply with any requirements imposed by EPA's response or cease all manufacture, import, processing, distribution, use and disposal of the PMN substance.

(k) Other Requirements. Regardless of the satisfaction of any other conditions in this Testing section, the Company must continue to obey all the terms of this Consent Order until otherwise notified in writing by EPA. The Company may, based upon submitted test data or other relevant information, petition EPA to modify or revoke provisions of this Consent Order pursuant to Part VI. of this Consent Order.

RISK NOTIFICATION

(a) If as a result of the test data required under the terms of this Order, the Company becomes aware that any of the PMN substance may present a risk of injury to human health or the environment (or is so notified by EPA), the Company must incorporate this new information, and any information on methods for protecting against such risk, into a Material Safety Data Sheet

("MSDS") for those PMN substance, as described in 40 CFR section 721.72(c), within 90 days from the time the Company becomes aware of the new information. If the PMN substance are not being manufactured, imported, processed, or used in the Company's workplace, the Company must add the new information to an MSDS before the PMN substance are reintroduced into the workplace.

(b) The Company must ensure that persons who will receive the PMN substance from the Company for either commercial or industrial use, or who have received the PMN substance from the Company for either commercial or industrial use, within 5 years from the date the Company becomes aware of the new information described in paragraph (a) of this section, are provided an MSDS containing the information required under paragraph (a) within 90 days from the time the Company becomes aware of the new information.

III. RECORDKEEPING

(a) Records. The Company shall maintain the following records until 5 years after the date they are created and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

(1) Exemptions. Records documenting that the PMN substance did in fact qualify for any one or more of the exemptions described in Section I, Paragraph (b) of this Order. Such records must satisfy all the statutory and regulatory recordkeeping requirements applicable to the exemption being claimed by the Company. Any amounts or batches of the PMN substance eligible for the Export exemption in Section I, Paragraph (b)(1) of this Order, are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the

date of their creation, copies of the export label and export notice to EPA, required by TSCA sections 12(a)(1)(B) and 12(b), respectively. Any amounts or batches of the PMN substance eligible for the Research and Development exemption in Section I, Paragraph (b)(2) of this Order, are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, the records required by 40 CFR 720.78(b). For any amounts or batches of the PMN substance claimed to be eligible for any other exemption described in Section I, Paragraph (b) of this Order, the Company shall keep records demonstrating qualification for that exemption as well as the records specified in paragraphs (2) and (3) below, but is exempt from the other record keeping requirements in this Record keeping section;

(2) Records documenting compliance with the Chemical Synthesis and Composition section of this Order, including the results from routine and quarterly analysis of representative samples of the starting material, [ ], and at start-up and annually thereafter of the Initially Isolated Formulations of the PMN substance.

(3) Records documenting compliance with the Manufacturing, Distribution, and Testing sections of this Order.

(4) Records documenting the manufacture and importation volume of the PMN substance and the corresponding dates of manufacture and import.

(5) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture or import to whom the Company directly sells or transfers the PMN substance, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date, wherein transfer does not include the distribution of small sample quantities (less than [ ] kilograms annually) of the PMN substance

without charge.

(6) Records documenting the address of all sites of manufacture, import, processing, and use;

(7) Copies of material safety data sheets required by the Risk Notification section of this Order;

(8) Copies of any Transfer Documents and notices required by the Successor Liability section of this Order, if applicable; and

(9) The Company shall keep a copy of this Order at each of its sites where the PMN substance are manufactured, processed, or used.

(b) Applicability. The provisions of this Record keeping Section are applicable only to activities of the Company and its Contract Manufacturer, if applicable, and not to activities of the Company's customers.

(c) OMB Control Number. Under the Paperwork Reduction Act and its regulations at 5 CFR Part 1320, particularly 5 CFR 1320.5(b), the Company is not required to respond to this "collection of information" unless this Order displays a currently valid control number from the Office of Management and Budget (OMB), and EPA so informs the Company. The "collection of information" required in this TSCA §5(e) Consent Orders has been approved under currently valid **OMB Control Number 2070-0012.**

IV. REQUESTS FOR PRE-INSPECTION INFORMATION

(a) EPA's Request for Information. Pursuant to section 11 of TSCA and 40 CFR 720.122, EPA

may occasionally conduct on-site compliance inspections of Company facilities and conveyances associated with the PMN substance. To facilitate such inspections, EPA personnel may contact the Company in advance to request information pertinent to the scheduling and conduct of such inspections. Such requests may be written or oral. The types of information that EPA may request may include, but are not limited to, the following:

(i) Expected dates and times when the PMN substance will be in production within the subsequent 12 months;

(ii) Current workshift schedules for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;

(iii) Current job titles or categories for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;

(iv) Existing exposure monitoring data for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;

(v) Records required by the Record keeping section of this Order; and/or

(vi) Any other information reasonably related to determining compliance with this Order or conducting an inspection for that purpose.

(b) Company's Response. The Company shall respond to such requests within a reasonable period of time, but in no event later than 30 days after receiving EPA's request. When requested in writing by EPA, the Company's response shall be in writing. To the extent the information is known to or reasonably ascertainable to the Company at the time of the request, the Company's response shall demonstrate a good faith effort to provide reasonably accurate and detailed answers to all of EPA's requests.

(c) Confidential Business Information. Any Confidential Business Information (CBI) that the Company submits to EPA pursuant to paragraph (b) shall be protected in accordance with §14 of TSCA and 40 CFR Part 2.

V. SUCCESSOR LIABILITY UPON TRANSFER OF CONSENT ORDER

(a) Scope. This section sets forth the procedures by which the Company's rights and obligations under this Order may be transferred when the Company transfers its interests in the PMN substance, including the right to manufacture the PMN substance, to another person outside the Company (the "Successor in Interest").

(b) Relation of Transfer Date to Notice of Commencement ("NOC").

(1) Before NOC. If the transfer from the Company to the Successor in Interest is effective before EPA receives a notice of commencement of manufacture ("NOC") for the PMN substance from the Company pursuant to 40 CFR 720.102, the Successor in Interest must submit new PMNs to EPA and comply fully with Section 5(a)(1) of TSCA and 40 CFR part 720 before commencing manufacture or import of the PMN substance.

(2) After NOC. If the transfer from the Company to the Successor in Interest is effective after EPA receives a NOC, the Successor in Interest shall comply with the terms of this Order and shall not be required to submit new PMNs to EPA.

(c) Definitions. The following definitions apply to this Successor Liability section of the Order:

(1) "Successor in Interest" means a person outside the Company who has acquired the

Company's full interest in the rights to manufacture the PMN substance, including all ownership rights and legal liabilities, through a transfer document signed by the Company, as transferor, and the Successor in Interest, as transferee. The term excludes persons who acquire less than the full interest of the Company in the PMN substance, such as a licensee who has acquired a limited license to the patent or manufacturing rights associated with the PMN substance. A Successor in Interest must be incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(3).

(2) "Transfer Document" means the legal instrument(s) used to convey the interests in the PMN substance, including the right to manufacture the PMN substance, from the Company to the Successor in Interest.

(d) Notices.

(1) Notice to Successor in Interest. On or before the effective date of the transfer, the Company shall provide to the Successor in Interest, by registered mail, a copy of the Consent Order and the "Notice of Transfer" document which is incorporated by reference as Attachment B to this Order.

(2) Notice to EPA. Within 10 business days of the effective date of the transfer, the Company shall, by registered mail, submit the fully executed Notice of Transfer document to: U.S. Environmental Protection Agency, New Chemicals Branch (7405), 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460.

(3) Transfer Document. Copies of the Transfer Document must be maintained by the Successor in Interest at its principal place of business, and at all sites where the PMN substance are manufactured or imported. Copies of the Transfer Document must also be made available for

inspection pursuant to Section 11 of TSCA, must state the effective date and time of transfer, and must contain provisions which expressly transfer liability for the PMN substance under the terms of this Order from the Company to the Successor in Interest.

(e) Liability.

(1) The Company shall be liable for compliance with the requirements of this Order until the effective date and time of the transfer described above.

(2) The Successor in Interest shall be liable for compliance with the requirements of this Order effective as of the date and time of transfer.

(3) Nothing in this section shall be construed to prohibit the Agency from taking enforcement action against the Company after the effective date of the transfer for actions taken, or omissions made, during the time in which the Company manufactured, processed, used, distributed in commerce, or disposed of the PMN substance pursuant to the terms of this Consent Order.

(f) Obligations to Submit Test Data under Consent Order. If paragraph (d) of the Testing section of this Consent Order requires the Company to submit test data to EPA at a specified production volume ("test trigger"), the aggregate volume of the PMN substance manufactured and imported by the Company up to the date of transfer shall count towards the test trigger applicable to the Successor in Interest.

VI. MODIFICATION AND REVOCATION OF CONSENT ORDER

The Company may petition EPA at any time, based upon new information on the health

effects of, or human exposure to, the PMN substance, to modify or revoke substantive provisions of this Order. The exposures and risks identified by EPA during its review of the PMN substance and the information EPA determined to be necessary to evaluate those exposures and risks are described in the preamble to this Order. However, in determining whether to amend or revoke this Order, EPA will consider all relevant information available at the time the Agency makes that determination, including, where appropriate, any reassessment of the test data or other information that supports the findings in this Order, an examination of new test data or other information or analysis, and any other relevant information.

EPA will issue a modification or revocation if EPA determines that the activities proposed therein will not present an unreasonable risk of injury to health or the environment and will not result in significant or substantial human exposure or substantial environmental release in the absence of data sufficient to permit a reasoned evaluation of the health or environmental effects of the PMN substance.

In addition, the Company may petition EPA at any time to make other modifications to the language of this Order, including modifications to production volume limits and time periods for submission of reports and data which are necessary due to no fault of, or circumstances beyond the control of, the Company. EPA in its sole discretion, may issue such a modification if EPA determines that the modification is useful, appropriate, and consistent with the structure and intent of this Order as issued.

VII. EFFECT OF CONSENT ORDER

(a) Waiver. This Order is effective when signed below by both parties and received by EPA. By consenting to the entry of this Order, the Company waives its rights to file objections to this Order pursuant to section 5(e)(1)(C) of TSCA, to receive service of this Order no later than 45 days before the end of the review period pursuant to section 5(e)(1)(B) of TSCA, and to challenge the validity of this Order in any subsequent action. Consenting to the entry of this Order, and agreeing to be bound by its terms, do not constitute an admission by the Company as to, the facts or conclusions underlying the Agency's determinations in this proceeding. This waiver does not affect any other rights that the Company may have under TSCA.

(b) CBI Brackets. By signing this Order, the Company represents that it has carefully reviewed this document and hereby agrees that all information herein claimed as confidential by the Company (per section 14 of TSCA, 40 CFR Part 720 Subpart E, and 40 CFR Part 2) is correctly identified within brackets and that any information that is not bracketed is not claimed as confidential. To make this document available for public viewing, EPA will remove only the information contained within the brackets.

15 August 2013
Date

Maria J. Doa
Maria J. Doa, Ph.D.
Director
Chemical Control Division
Office of Pollution Prevention and Toxics

19 Aug 2013
Date

Name: [ ]

Title: [ ]

Company: [ ]

ATTACHMENT A

DEFINITIONS

[Note: The attached Order may not contain some of the terms defined below.]

"Chemical name" means the scientific designation of a chemical substance in accordance with the nomenclature system developed by the Chemical Abstracts Service's rules of nomenclature, or a name which will clearly identify a chemical substance for the purpose of conducting a hazard evaluation.

"Company" means the person or persons subject to this Order.

"Commercial use" means the use of a chemical substance or any mixture containing the chemical substance in a commercial enterprise providing saleable goods or a service to consumers (e.g., a commercial dry cleaning establishment or painting contractor).

"Common name" means any designation or identification such as code name, code number, trade name, brand name, or generic chemical name used to identify a chemical substance other than by its chemical name.

"Consumer" means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

"Consumer product" means a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation.

"Container" means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

"Contract Manufacturer" means a person, outside the Company, who is authorized to manufacture and import the PMN substance under the conditions specified in Part II. of this Consent Order and in the Consent Order for Contract Manufacturer.

"Final Formulation of the PMN substance" means the formulated dispersion or solution of the PMN substance in the form in which it is sold to customers outside the Company or transferred to a different business unit within the Company. The term does not include intermediate dilutions of the PMN substance that are intended only for use within the Company for further dilution prior to sale.

"Identity" means any chemical or common name used to identify a chemical substance or

a mixture containing that substance.

"Immediate use." A chemical substance is for the "immediate use" of a person if it is under the control of, and used only by, the person who transferred it from a labeled container and will only be used by that person within the work shift in which it is transferred from the labelled container.

"Industrial use." An industrial use is a use at a site at which one or more chemical substances or mixtures are manufactured (including imported) or processed.

"Initially Isolated Formulations of the PMN substance" means a common intermediate PMN formulation, as it exists when first produced and isolated after the polymer manufacturing process, that can be further processed or repackaged at the direction of the Company to result ultimately in one or more final formulations of the PMN substance.

"Manufacture" means to produce or manufacture in the United States or import into the customs territory of the United States.

"Manufacturing stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of manufacture, including the cleaning of equipment.

"MSDS" means material safety data sheet, the written listing of data for the chemical substance.

"NIOSH" means the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services.

"Non-enclosed process" means any equipment system (such as an open-top reactor, storage tank, or mixing vessel) in which a chemical substance is manufactured, processed, or otherwise used where significant direct contact of the bulk chemical substance and the workplace air may occur.

"Non-industrial use" means use other than at a facility where chemical substances or mixtures are manufactured, imported, or processed.

"PMN substance" means the chemical substance (see TSCA s. 3(2)) described in the Premanufacture notices submitted by the Company relevant to this Order.

"Process stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of processing, including the cleaning of equipment.

"Scientifically invalid" means any significant departure from the EPA-approved protocol or the Good Laboratory Practice Standards at 40 CFR Part 792 without prior or subsequent Agency approval that prevents a reasoned evaluation of the health or environmental effects of the

PMN substance.

"Scientifically equivocal data" means data which, although developed in apparent conformity with the Good Laboratory Practice Standards and EPA-approved protocols, are inconclusive, internally inconsistent, or otherwise insufficient to permit a reasoned evaluation of the potential risk of injury to human health or the environment of the PMN substance.

"Sealed container" means a closed container that is physically and chemically suitable for long-term containment of the PMN substance, and from which there will be no human exposure to, nor environmental release of, the PMN substance during transport and storage.

"Use stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of industrial, commercial, or consumer use.

"Workplace" means an establishment at one geographic location containing one or more work areas.

ATTACHMENT B

NOTICE OF TRANSFER
OF
TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

_____ _____
Company (Transferor) PMN Number

1. Transfer of Manufacture Rights. Effective on _____, the Company did sell or otherwise transfer to _____, ("Successor in Interest") the rights and liabilities associated with manufacture of the above-referenced chemical substance, which was the subject of a premanufacture notice (PMN) and is governed by a Consent Order issued by the U.S. Environmental Protection Agency (EPA) under the authority of §5(e) of the Toxic Substances Control Act (TSCA, 15 U.S.C. §2604(e)).

2. Assumption of Liability. The Successor in Interest hereby certifies that, as of the effective date of transfer, all actions or omissions governed by the applicable Consent Order limiting manufacture, processing, use, distribution in commerce and disposal of the PMN substance, shall be the responsibility of the Successor in Interest. Successor in Interest also certifies that it is incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(3).

3. Confidential Business Information. The Successor in Interest hereby:

___ reasserts,

___ relinquishes, or

___ modifies

all Confidential Business Information (CBI) claims made by the Company, pursuant to Section 14 of TSCA and 40 CFR part 2, for the PMN substance(s). Where "reasserts" or "relinquishes" is indicated, that designation shall be deemed to apply to all such claims. Where "modifies" is indicated, such modification shall be explained in detail in an attachment to this Notice of Transfer. Information which has been previously disclosed to the public (e.g., a chemical identity that was not claimed as CBI by the original submitter) would not subsequently be eligible for confidential treatment under this Notice of Transfer.

TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

NOTICE OF TRANSFER
(continued)

Company (Transferor) PMN Number

Signature of Authorized Official Date

Printed Name of Authorized Official

Title of Authorized Official

Successor in Interest

Signature of Authorized Official Date

Printed Name of Authorized Official

Title of Authorized Official

Address

City, State, Zip Code

TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

NOTICE OF TRANSFER
(continued)

_____
Successor's Technical Contact

_____
Address

_____
City, State, Zip Code

_____
Phone